REMARKS

Prior to this amendment, claims 25, 26, 32, 33, 39-41 and 44-46 were pending in this application, with claims 45 and 46 withdrawn from consideration. The present amendment amends claims 25-26 and 32-33. Upon entry of this amendment, claims 25, 26, 32, 33, 39-41 and 44-46 will be pending, with claims 45 and 46 withdrawn from consideration.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is discussed below.

Claims 25-26 and 32-33 are objected to because of informalities. (Office action paragraph no. 5)

The Examiner objects to the claims because "herpes virus" is not capitalized as "Herpes virus".

The objection is overcome by the amendment to the claims, capitalizing "Herpes virus". Support for this amendment may be found in the original presentation of this term, in which "Herpesvirus" was capitalized. Applicant submits, however, that this term may be either capitalized or not capitalized, and the meaning is unchanged by the amendment to capitalize the term.

Claims 25-26, 32-33, 39-41 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. (Office action paragraph no. 6)

The rejection under 35 U.S.C. 112, first paragraph, is respectfully traversed, and

reconsideration of the rejection is requested.

The Examiner states the basis of the rejection on page 6, line 7, of the Office action:

> "The generic statements drawn to the encoding DNA, the antigenic protein isolated from *Mycoplasma gallisepticum* and the signal polypeptide of Herpes virus glycoprotein B do not provide ample written description for fusion protein since the claims do not describe structural features."

Applicant respectfully disagrees with the Examiner's contention that: "the claims do not describe structural features", noting that the Examiner does not clearly indicate what structural features appear to be lacking from the claim.

The term "fusion protein," referred to by the Examiner, appears in claim 25 in the preamble and in the last clause of the claim. Applicant submits that the body of claim 25 recites the **structure** of the fusion protein that the claimed "recombinant Avipox virus" codes for. This fusion protein has two parts: (i) an antigenic protein and (ii) a signal polypeptide of herpes virus glycoprotein B protein, and the claim further recites how these are ligated. (This is similarly the case in claims 26, 32, and 33.)

The Examiner goes on to state that:

> "Furthermore, the statements regarding the encoding DNA and the antigenic protein being isolated from *Mycoplasma gallisepticum* which cause an antibody-antigen reaction with *Mycoplasma gallisepticum* infected serum do not sufficiently provide ample written description since this only describes the function of the DNA and antigenic protein."

Here, the Examiner refers to the characterization of the antigenic protein (i) in the claims.

The Examiner appears to be stating that the definition of the antigenic protein is functional, and therefore inadquate.

In response, Applicant submits that the definition of the antigenic protein, as recited in the claims, is **not** just the "function" of the antigenic protein. Rather, the recitation of "an antigenic protein isolated from *Mycoplasma gallisepticum* that causes an antibody-antigen reaction with *Mycoplasma gallisepticum* infected serum" is a definition of a class of proteins based on a specific, assayable, **characteristic** that identifies them. This characteristic clearly distinguishes the recited antigenic protein from other proteins. As such, this recitation **does** provide adequate written description, according to the portion of *Regents of the University of California v. Eli Lilly & Co.* (43 USPQ2d 1398) cited by the Examiner on page 5 of the Office action.

In addition, Applicant notes that the recitation in the claims of "an antigenic protein isolated from *Mycoplasma gallisepticum* that causes an antibody-antigen reaction with *Mycoplasma gallisepticum* infected serum" is similar to that in some issued U.S. Patents. For instance, claims 1 and 5 of U.S. Patent No. 5,621,076 recite very similar wording: "An isolated and purified polypeptide which reacts with anti-*Mycoplasma gallisepticum* chicken sera through an antigen-antibody reaction." Claims 8 and 10 of U.S. Patent No. 5,871,742 also recite similar wording. Copies of these two U.S. Patents are enclosed herewith for the Examiner's convenience. These examples demonstrate that one of skill in the art would understand the scope and meaning of the recitation regarding the antigen in the present claims.

Furthermore, Applicant would like to point out that Example 4 of the present specification

actually confirmed the antibody-antigen reaction between the antigenic protein and Mycoplasma gallisepticum infected serum, again clearly explaining this term definition.

On page 7, line 4, the Examiner states:

> "Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the protein beyond [what is] disclosed in the examples in the specification."

Applicant submits that the Examiner's point here is not completely clear, but appears to be related to the above discussed issue. In response, what the Examiner refers to as the "function" of the antigenic protein is, in fact, an identifying **characteristic** that serves as a limitation on the possible proteins that can be used in the claim. The biological "function" of the antigenic protein is, in fact, **not explicitly recited** in the claims, although one function can be inferred and is explained in the specification. The "function" does not affect the recitation of the claims, and Applicant submits that remarks regarding the "function" are irrelevant given the recitation of the present claims.

The Examiner also states: "Moreover, the specification [lacks] sufficient variety of species to reflect this variance in the genus since the specification does not provide more than two examples." The Examiner appears to be stating that the claims should somehow be limited to SEQ ID NOs: 1 and 3, which are hybrid DNA sequences encoding fusion proteins of the invention (see specification, page 10).

In response, Applicant argues that SEQ ID NOs 1 and 3 are only **exemplary**, and are not

necessary for written description of the fusion protein of the present claims. Clearly, the description in the specification, in disclosing that the antigenic protein is a protein isolated from *M gallisepticum*, is describing a genus of proteins larger than the antigenic protein portion in SEQ ID NOs: 1 and 2. It is well established that written description is not limited to the working examples.

In regard to the size of the "genus" of proteins encompassed by the "antigenic protein", Applicant notes that the genome size of *Mycoplasma gallisepticum* is approximately 800kbp, from which it is expected that Mycoplasma gallisepticum expresses less than 500 proteins in total. Among them, perhaps 100 or 200 proteins are expected to react with the *Mycoplasma gallisepticum* infected serum. Although this is only a rough estimate, Applicant submits that this is not an exceptionally broad genus, and is well described, as discussed above.

Applicant disagrees with the Examiner's remarks at the bottom of page 7 that Applicant is only claiming "a result one might achieve if one made that invention". **The present claims do not recite a "goal" or a hypothetical "result"**, but rather recite a product with specific structural limitations.

Applicant further notes that the claimed invention is directed to a specific and unique combination of the gB signal polypeptide with the MG antigenic protein, and **not simply the kind of the gB signal polypeptide or MG antigenic protein used, nor the kind or the structural feature of the fusion protein containing the gB signal polypeptide and MG antigenic protein.**

Applicants submit that a person skilled in the art can clearly recognize the gB signal

polypeptide and MG antigenic protein used in the claimed invention and understand the described structure of the fusion protein containing them.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 25-26, 32-33, 39-41 and 44 are rejected under 35 U.S.C. 112, second paragraph, s being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office action paragraphs no. 7-8)

The rejection under 35 U.S.C. 112, second paragraph, is respectfully traversed, and reconsideration and withdrawal of the rejection are requested.

The Examiner refers to the preamble phrase: "A recombinant Avipox virus having a DNA coding", suggesting eliminating the second article "a" to read: "A recombinant Avipox virus having DNA coding ..." However, Applicant believes that this amendment is unnecessary.

It is true that the term "DNA" refers most correctly to the class of compounds, and is commonly used in expressions such as "a DNA molecule". However, Applicant believes that the usage in the present claims would be well understood by one of skill in the art.

Moreover, in claims 32 and 33, the DNA of the preamble used as antecedent for "said DNA" later in the claim. In these claims, since the definite article "said" is used later in the claim, the indefinite article "a" in the preamble is appropriate.

The Examiner notes that dependent claims 39-41 use the indefinite article "A" as the first word in the preamble. However, either the indefinite article "A" or the definite article "The" is

permissible here. Although the MPEP does not discuss this issue directly, the analogous use of the indefinite article can be seen in the examples of proper multiple-dependent claim language in MPEP 608.01(n)(A). Applicant submits that the choice of "A" or "The" here is not an issue of indefiniteness under 35 U.S.C. 112, second paragraph.

In view of the aforementioned amendments and accompanying remarks, the claims, as amended, are in condition for allowance, which action, at an early date, is requested.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the Applicant's undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the Applicant respectfully petitions for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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PATENT TRADEMARK OFFICE

Enclosures: U.S. Patent No. 5,621,076
U.S. Patent No. 5,871,742

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